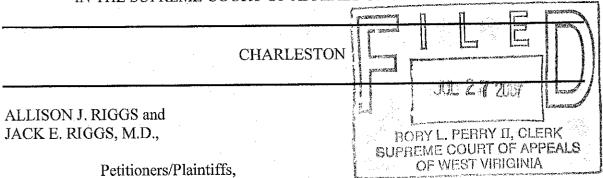
IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA



v.

From the Circuit Court of Monongalia County, West Virginia CIVIL ACTION NO. 01-C-147

WEST VIRGINIA UNIVERSITY HOSPITALS, INC.,

Respondent/Defendant.

## AMICI BRIEF IN SUPPORT OF BRIEF OF APPELLEE, WEST VIRGINIA UNIVERSITY HOSPITALS, INC.

### BRIEF OF AMICI CURIAE, WEST VIRGINIA HOSPITAL ASSOCIATION WEST VIRGINIA STATE MEDICAL ASSOCIATION

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### KIND OF PROCEEDING AND NATURE OF THE RULING BELOW

The instant matter is before the Court on an appeal filed by Plaintiffs following a trial on the merits, a Plaintiffs' verdict and the Court's entry of the final judgment order, which reduced Plaintiffs' verdict in accord with the 1986 Medical Professional Liability Act's ("MPLA") one million dollar limit on non-economic damages.

Amici Curiae joins with appellee, West Virginia University Hospital, Inc., in urging this Court to affirm the Order of the Circuit Court finding that the MPLA is applicable to the instant matter.

### **INTRODUCTION**

The West Virginia Hospital Association ("WVHA") is a non-profit, voluntary, professional association. For eighty-one years, the WVHA has represented its member hospitals and health systems across the continuum of care. WVHA supports its members in achieving a strong, healthy West Virginia through advocacy, education, information, and technical assistance and by being a catalyst for effective change through collaboration, consensus building and a focus on desired outcomes. The members of the WVHA believe it is in the best interest of the health care community to have a strong, healthy West Virginia. The mission of the WVHA is to support its member hospitals and health systems in achieving that goal. The WVHA monitors court decisions impacting its members and has filed *amicus* briefs with this Court in previous cases. WVHA members have a special interest in this matter in that they participated in advancing reforms to the Medical Professional Liability Act, have experienced a reduction in costs and stabilizing insurance market as a result thereof, and are directly affected by this Court's decision.

WVHA members believe it is critical to the availability and affordability of health care that the MPLA reforms be maintained.

The West Virginia State Medical Association ("WVSMA") is a non-profit, voluntary, professional association of physicians who strive to extend medical knowledge and advance medical science, promote public health, work to secure the enactment and enforcement of just medical laws, promote the general welfare of the profession, protect patient privacy, promote the prevention and cure of disease, and improve the quality of life in the State. The approximately 2200 members of WVSMA include active and retired physicians, residents and medical students.

West Virginia physicians have a special interest in this matter as they actively worked on each version of the Medical Professional Liability Act seeking to educate the legislature in its deliberations of these complex matters. Physicians seek to protect the public through available and affordable liability insurance as well as to create a climate conducive to attracting and retaining qualified physicians. WVSMA members believe it is critical to the availability and affordability of health care that the MPLA reforms be maintained.

### RELIEF SOUGHT BY AMICI CURIAE

WVHA and WVSMA urge this Court to affirm the order of the Circuit Court finding the MPLA applicable to the instant case, as a hospital's infection control activity is a health care service as defined by the MPLA.

### ARGUMENT AND LEGAL AUTHORITY

Amici Curiae, WVHA and WVSMA, offer this brief in support of Appellee, West Virginia University Hospitals, Inc. ("WVUH"). WVHA and WVSMA join in the arguments of WVUH that infection control is and cannot be anything other than part of every hospital's health care services provided on behalf of patients; and therefore, claims arising from hospital's infection control practices are governed by the provisions of the MPLA.

A Health Care Facility's Infection Control Falls Within The MPLA's Definition Of Health Care As It Is An Act Or Treatment Performed Or Furnished By A Health Care Provider On Behalf Of A Patient During The Patient's Medical Care, Treatment Or Confinement.

### A. What claims fall within the MPLA?

To be governed by the MPLA, a claim must fall within the definition of "medical professional liability." The MPLA defines this as "any liability for damages resulting from the death or injury of a person for any tort or breach of contract based on health care services rendered, or which should have been rendered, by a health care provider or health care facility to a patient." W.Va. Code §55-7B-2(d)(1986). It is undisputed that WVUH is a health care facility. It is also undisputed that services were rendered by the facility to the plaintiff who was a registered, hospital patient. Thus, the actual issue is whether the hospital's infection control can properly be defined as "health care" under the MPLA. Health care is defined broadly as "any act or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to or on behalf of a patient during the patient's medical care, treatment or confinement." W.Va. Code §55-7B-2(a)(1986).

B. The provision of health care is not, nor can it be, limited to direct handson care of a patient.

The Appellant takes the position that there are no allegations that WVUH negligently rendered care directly to Allison Riggs, that no member of WVUH's Department of Infection Control ever treated Allison Riggs nor consulted on her case. As such, Appellant asserts that there were no health care services rendered to Allison Riggs such as to implicate the MPLA. However, the scope of medical professional liability cannot be, and is not, so narrowly defined. The act itself states that "health care" means "any act or treatment performed or furnished, or which should have been performed or furnished, by any health care provider [which includes a health care facility] for, to or on behalf of a patient during the patient's medical care, treatment or confinement." W.Va. Code §55-7B-2(a)(Emphasis added). Professional infection control activity is an essential element of hospital medical services provided to every patient.

Appellant and amicus, West Virginia Association for Justice ("WVAJ"), fail to address this critical piece of the definition for "health care." Instead, Appellant and WVAJ take the position that there has to be some type of "hands-on" care for the MPLA provisions to be triggered. No where in the MPLA is there any such language. "Statutes in derogation of the common law are allowed effect only to the extent clearly indicated by the terms used. Nothing can be added otherwise than by necessary implication arising from such terms." *Phillips v. Larry's Drive-In Pharmacy, Inc.*, \_\_\_\_\_ S.E.2d \_\_\_\_\_, Syl. Pt. 4 (W. Va. Slip Op. 33194, filed June 28, 2007). Appellant's and the WVAJ's reliance upon *Phillips v. Larry's Drive-In Pharmacy, Inc.*, for the proposition that the MPLA provisions apply only to claims where there has been hands on care, is an over-

reaching interpretation of this Court's decision. The decision in *Phillips* turns, not on whether a pharmacy provides health care to a patient, but on the simple fact that pharmacies were not listed in W.Va. Code §55-7B-2(c). Specifically, this Court concluded: "We believe that there is no better definition of what constitutes the medical care community, and therefore what groups and individuals are included as 'health care provider[s]' under the MPLA, than the unambiguous and exclusive list of defined providers in *W.Va. Code*, 55-7B-2(c)." *Id.* Thus, because certain medical professionals are specifically included under the MPLA but pharmacies are not included, the Court held that selling prescriptions to a customer is not conduct covered by the provisions of the MPLA.

This Court did briefly, and incidentally as *dicta*, discuss whether a pharmacy renders health care services to a patient. However, this Court did not hold that health care can only mean direct hands-on care to a patient. Rather, the Court in analyzing the *Short v. Appalachian OH-9*, *Inc.*, 203 W.Va. 246, 507 S.E.2d 124 (1998) (case involving emergency medical technicians "EMT"), distinguished *Phillips* from *Short* by noting that EMTs are more akin to the creation of a doctor-patient relationship because EMTs provide direct hands on care to a patient whereas people go to pharmacies largely just to buy a product. *Id.* This Court, neither in *Phillips* nor *Short* held that hands-on care is the dividing line between what is and what is not to be included with the MPLA.

Appellant also cites *Boggs v. Camden-Clark Memorial Hospital Corp.*, 216 W.Va. 656, 609 S.E.2d 917 (2004), in support of their assertion that hospital infection control activity is not health care covered by the provisions of the MPLA. However, as this Court pointed out in *Gray v. Mena*, 218 W.Va. 564, 625 S.E.2d 326 (2005):

This Court's opinion in *Boggs v. Camden-Clark Memorial Hospital Corp.*, 216 W.Va. 656, 609 S.E.2d 917 (2004), is clarified by recognizing that the West Virginia Legislature's definition of medical professional liability, found in West Virginia Code § 55-7B-2(i) (2003) (Supp.2005), includes liability for damages resulting from the death or injury of a person for any tort based upon health care services rendered or which should have been rendered. To the extent that *Boggs* suggested otherwise, it is modified.

Id. at Syl. Pt. 4 (emphasis added). As previously stated, the MPLA defines "health care" to include acts furnished to or on behalf of a patient.

Appellants and WVAJ's reliance on this Court's citation in *Phillips* to *Kroger Co. v. Estate of Hinders*, 773 N.E.2d 303, 306-7 (Ind.Ct.App. 2002) is also overreaching. The pertinent language from *Kroger* is as follows:

In every relationship between a patient and <u>one of the listed health care providers</u> under Indiana Code section 34-18-2-14, independent medical treatment is an important component of the health care provided. This characteristic is lacking in the relationship between a pharmacist and a customer simply requesting that a prescription is dispensed.

Phillips (emphasis added)(quoting Kroger at 306-7). First and foremost, a hospital is one of the named health care providers under the MPLA. Second, despite assertions to the contrary, to fall within the MPLA, a claim does not have to involve direct health care services from a health care provider to a patient or a "laying on of hands", as long as it is a health care service on behalf of patients during their medical care, treatment or confinement. It belies common sense and policy interests to suggest that infection control methods and protocols are somehow not performed on behalf of hospitalized patients.

This was recently confirmed by the U.S. District Court for the Northern District of West Virginia. In *Miller v. The American Red Cross*, Plaintiff had a blood transfusion while undergoing a lung biopsy at Defendant hospital. The blood that was used was

collected, screened and/or provided by the American National Red Cross (Red Cross). Following the surgery, Plaintiff was contacted by Red Cross and advised that the blood he had been given had been tainted with malaria. Plaintiff filed suit arguing that the defendant hospital failed to properly collect, screen and/or prepare the blood it provided to patients. Plaintiff also argued that the hospital was negligent with respect to its policies and procedures to ensure that the blood was not tainted. *Miller v. The American Red Cross*, No. Civ. A. 1:05CV71, 2006 WL 473750 at \*1 (N.D.W.Va. 2006)(unpublished), *see* appendix, Exhibit A.

In *Miller*, the defendant hospital filed a motion to dismiss for plaintiff's failure to follow the now existing pre-suit notice of claim/screening certificate of merit requirements under W.Va. Code §55-7B-6(2003). In response, Plaintiff argued that his claims did not fall within the scope of the MPLA. Specifically, the plaintiff asserted that his alleged injury was not a tort of negligence based on health care services rendered during a blood transfusion. Plaintiff further asserted that he was not claiming that the blood transfusion was performed negligently. As such, Plaintiff argued that his claims fell outside the scope of the MPLA. *See id* at \*1-2.

The Honorable Frederick P. Stamp, Jr. of the United States District Court for the Northern District of West Virginia disagreed with Plaintiff. Judge Stamp began by noting that "[w]hile the plaintiff is not arguing the actual blood transfusion was negligently performed, he is arguing that the procedure for screening the blood that was provided as part of a health care service rendered to a patient was negligently screened, collected and/or prepared." *Id.* Judge Stamp further cited the public policy of the MPLA as stating "that, 'as in every human endeavor the possibility of injury or death

from negligent conduct commands that protection of the public served by health care providers be recognized as an important state interest." *Id.* at 3 (*quoting* W.Va. Code §55-7B-1). In doing so, the Court noted that collecting, screening and/or preparing blood that is used at a health care facility is an important state interest and thus falls within the public policy interests of the MPLA. *Id.* Just as blood handling is a health care service governed by the provisions of the MPLA, so too is infection control.

In the instant case, as noted by WVUH in its Response to Petition, "[t]he primary objective of hospital infection control is detection and prevention of nosocomial infections in patients." Thus, the provision of infection control in the hospital setting, like the screening, collecting, and preparing of blood products, is done so as part of health care services rendered to a patient during that patient's medical care, treatment or confinement. Furthermore, like blood products, it can hardly be said that providing infection control services is not an important state interest.

Furthermore, Courts in other jurisdiction have ruled that the failure to abide by infection-control policies is directly related to the quality of medical care and is thus within the realm of medical negligence. *See Smith v. Tenet Healthsystems SL, Inc.*, 436 F.3d 879 (8<sup>th</sup> Cir. 2006). In *Tenet*, a patient filed suit against a hospital, physician, and the physician's employer arising from the amputation of the patient's right leg. The plaintiff alleged, inter alia, that the defendants failed to comply with infection-control policies. Prior to trial, the district court granted summary judgment to the defendants on this issue on the grounds that the plaintiff failed to offer expert medical testimony. Plaintiff argued on appeal that he did not need an expert and that an ordinary negligence standard applied as opposed to a medical negligence standard. The Eighth Circuit Court

of Appeals disagreed stating that the ordinary negligence standard only applies to cases which involve liability for injuries that are not related to the provision of medical care. *Id.* at 888. *cf. Boggs v. Camden-Clark Memorial Hospital, Corp.*, 216 W.Va. 656, 609 S.E.2d 917 (2004). The Eighth Circuit held that the plaintiff's allegations that the health care providers failed to abide by infection-control policies are directly related to the quality of the patient's medical care and, as such, expert testimony was needed. *Id.* Much as the Eighth Circuit concluded, infection control at WVUH and at all hospitals is an important component in the delivery of quality health care rendered to or on behalf of a patient during a period of hospital confinement.

Similar to *Tenet Healthsystems*, in *Cashio v. Baton Rouge General Hospital*, 378 So.2d 182 (La.App. 1979), a Louisiana court addressed a claim by a patient against a hospital claiming damages from a "staph" infection acquired during heart surgery. An issue arose at the outset as to whether or not this was a medical malpractice claim subject to the Louisiana Medical Malpractice Act. The Court began by noting that there was no question that the defendant is a health care provider as defined by the act. *Id.* at 184. Plaintiff argued that his claim "is not based upon health care or professional services rendered but rather upon the duty owed by a premises owner." *Id.* The Court disagreed. While a hospital "may be liable as owner in situations outside of malpractice, such as in slip-and-fall and similar tort cases," claims involving a hospital's "furnishing of a clean and sterile environment for all patients....is squarely within the conduct classified by the Act as malpractice." *Id.* at 184-5.

<sup>&</sup>quot;'Health care provider' means a person corporation, facility or institution licensed by this state to provide health care or professional services as a physician, hospital, dentist, registered or licensed practical nurse, pharmacist, optometrist, podiatrist, chiropractor, physical therapist or psychologist, or an officer, employee or agent thereof acting in the course and scope of his employment." *Cashio* at 184, fn 3 (emphasis added)(*quoting* La.R.S. 40:1299.41A(1)).

In addition, in 2000, the United States District Court for the Southern District of Pennsylvania dealt with a case involving a patient who was involved in an automobile accident and suffered a herniated disc. *See Gahm v. Thomas Jefferson University Hospital*, 2000 WL 233247, Civ. A. No. 94-2050 (E.D.Pa. Feb. 29, 2000)(unpublished), *see* appendix, Exhibit B. Subsequently, the patient was admitted to the hospital where surgery was performed. Soon after the surgery, the patient asserted that he developed an infection. Plaintiff sued claiming that the infection was caused by the negligence of the hospital and its staff. The Court began at the outset by noting that this was a medical malpractice case. *See id.* at \*1. As such, the Court found that the plaintiff was required to have an expert witness. *See id.* at \*2. In that case, plaintiff's expert was critical only of the hospital's failure to properly classify the infection. That expert did not, however, opine "that the hospital's services, or lack of them, increased the chances of plaintiff's infection." *Id.* The Court held as follows:

This is a case in which expertise is essential. Expert medical testimony is necessary "when there is no common fund of knowledge from which laymen can reasonably draw the inference or conclusion of negligence."... Hospital infection control is a highly technical and complex area of knowledge. Accordingly, without an expert report stating the hospital was negligent, the motion for summary judgment must be granted.

Id. These cases demonstrate that health care is not confined to a physician or nurse standing over a patient providing direct hands-on care; nor can it be. Such an interpretation fails to take into consideration care that a radiologist provides on behalf of a patient. In the hospital setting, many times, if not most of the time, the radiologist will never see the patient or speak to them. Instead, he or she will be in a separate part of the hospital, or at a separate facility all together. The radiologist is not rendering care directly to a patient, but is rendering/performing a health care service on that patient's

behalf. *Cf.* W.Va. Code §55-7B-2(a). Similarly, a pathologist reviewing patients' pathological tissue and slides will often never see or speak to the patient. However, they are still rendering/performing a health care service on that patient's behalf. Likewise, a hospital may not be laying on hands when it engages in infection control activity, but it is a critical component of the hospital's delivery of health care rendered on behalf of a patient during the patient's confinement.

C. <u>Hospital infection control is a critical and necessary component of a hospital's delivery of care to a patient.</u>

According to the Center for Disease Control, CDC, in 1992, it was noted that nosocomial, or hospital acquired, infections affected more than 2 million patients annually and, at that time, cost more than \$4.5 billion dollars.<sup>2</sup> It remains a significant problem today. Specifically, the greatest infection risks in hospitals affect post-surgical patients, intensive care unit (ICU) patients and patients with serious diseases.<sup>3</sup>

In the 1950's, the issue of hospital acquired infections began to present as a major public health issue when staph infections "began to plague hospitals." Formal programs for infection control started to develop around this time and continuously evolved through the 1960s and 1970s. In the early 1970s, a study was begun by the CDC in an effort to evaluate how effective these newly developed infection surveillance and control

<sup>2</sup> See, CDC, Public Health Focus: Surveillance, Prevention, and Control of Nosocomial Infections, available at <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/00017800.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/00017800.htm</a>.

<sup>&</sup>lt;sup>3</sup> See, AHA, Statement of the American Hospital Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigation Hearing. Public Reporting on "Hospital-Acquired Infections" Empowering Consumers, Saving Lives, March 29, 2006, available at <a href="http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf">http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf</a>.

<sup>&</sup>lt;sup>4</sup> See Robert W. Haley, THE SENIC PROJECT. Study of the Efficacy of Nosocomial Infection Control (SENIC PROJECT). American Journal of Epidemiology, Vol. 111, No. 5, p. 473.

See, CDC, Public Health Focus: Surveillance, Prevention, and Control of Nosocomial Infections, available at <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/00017800.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/00017800.htm</a>.

programs were in combating nosocomial infection.<sup>6</sup> The findings of this study, also known as the Study on the Efficacy of Nosocomial Infection Control or SENIC, established the efficacy of infection-control programs in hospitals.<sup>7</sup> In fact, in 1976, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)<sup>8</sup> added to its standards for hospital accreditation the requirement of an infection surveillance and control program.<sup>9</sup> Currently, the West Virginia Code of State Rules regarding the licensing of hospitals mandate the following as it relates to hospitals and infection control:

- 7.4.a. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases.
- 7.4.b. The hospital shall have an active surveillance and education program for the prevention, early detection, control, and investigation of infections and communicable diseases.
- 7.4.c. The program shall include implementation of a nationally recognized system of infection control guidelines.
- 7.4.d. The program shall be both hospital-wide and program-specific and enforced by the individual designated by the medical staff.
- 7.5.e. The hospital staff shall designate a person or persons as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases for patients and personnel....

See, Code of State Rules §64-12-7.4.a-e. The purpose of this, as with the other provisions of the licensure rule, is "to ensure all West Virginia hospitals conform to a common set of standards and procedure. All standards and procedures are minimum

<sup>.6</sup> Id.

<sup>&</sup>lt;sup>7</sup> Id. See also, Robert J. Sharbaugh, Ph.D., An evaluation of the efficacy of a hospital infection control program, Am. J. Infect. Control, 1981 May; 9(2): 35-42 ("involvement of infection control personnel at all levels of patient care as part of a sophisticated hospital infection control program can result in a significant reduction in the incidence of nosocomial infections.") (emphasis added).

<sup>&</sup>lt;sup>8</sup> The Joint Commission is an independent, non-profit organization that evaluates and accredits approximately 15,000 health care organizations and programs within the United States. West Virginia University Hospitals is such an accredited facility. See, JCAHO, Facts about The Joint Commission, available at <a href="http://jointcommission.org/AboutUs/jointcommissi

<sup>&</sup>lt;sup>9</sup> See, CDC, Public Health Focus: Surveillance, Prevention, and Control of Nosocomial Infections, available at <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/00017800.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/00017800.htm</a>.

requirements whereby hospitals may be surveyed and evaluated to ensure the health and safety of all patients treated in West Virginia." See, W. Va. Code of State Rules §64-12-1.8 (emphasis added).

Since the 1950s, controlling and preventing infections has become a "patient safety priority for America's hospitals and permeate every aspect of hospital care." While individuals are exposed to bacteria and virus in their everyday environment, it becomes an even greater risk in the health care setting for two reasons. First, "[p]atients' immune systems may already be weakened by disease, injury or the medications and procedures being used to treat whatever has prompted them to seek care." Second, "people may come into contact with others infected by more powerful viruses and bacteria."

Combating these risks and improving the care rendered to patients via infection control is a complicated, daunting, and evolving area of health care. According to the CDC, "[t]ransmission of infectious agents within a healthcare setting requires three elements: a source (or reservoir) of infectious agents, a susceptible host with a portal entry receptive to the agent, and a mode of transmission for the agent." First and foremost, not all infections are the same. Infection control programs must understand the risks attendant with each type of infection, how it is spread, who is susceptible,

<sup>&</sup>lt;sup>10</sup> See, AHA, Statement of the American Hospital Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigation Hearing. Public Reporting on "Hospital-Acquired Infections" Empowering Consumers, Saving Lives, March 29, 2006, available at <a href="http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf">http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf</a>.

<sup>11</sup> Id.

<sup>12</sup> *Id.* 

<sup>&</sup>lt;sup>13</sup> See, CDC, Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007, available at, <a href="http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf">http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf</a>
<sup>14</sup> See, AHA, Statement of the American Hospital Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigation Hearing. Public Reporting on "Hospital-Acquired Infections" Empowering Consumers, Saving Lives, March 29, 2006, available at <a href="http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf">http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf</a>.

identify those who are susceptible, and how to prevent each type of infection based upon how it is spread. As stated by the CDC,

Several classes of pathogens can cause infection, including bacteria, viruses, fungi, parasites, and prions. The modes of transmission vary by type of organism and some infectious agents may be transmitted by more than one route: some are transmitted primarily by direct or indirect contact, (e.g. Herpes simplex virus [HSV], respiratory syncytial virus, Staphylococcus aureus), others by droplet, (e.g. influenza virus, B. pertussis) or airborne routes (e.g., M. tuberculosis). 15

In fact, in a recently published CDC guideline, the CDC lists over two hundred different types of infections along with each infection's precautions that should be used and the duration of time the precautions should be utilized.<sup>16</sup>

In addition to the difficulties associated with each infection being different, infection control programs are also faced with the continuous emergence of new diseases and the establishment of knowledge necessary to prevent the spread of those new diseases. For instance, in 2002, a new respiratory disease called Severe Acute Respiratory Syndrome, or SARS, emerged in China and spread to several countries. <sup>17</sup> A significant feature of SARS is its ability to transmit to a large number of healthcare personnel and patients. <sup>18</sup> Controlling it has required medical professionals to engage in early detection, screening and the use of multiple precautions. <sup>19</sup>

<sup>&</sup>lt;sup>15</sup> See, CDC, Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007, available at, <a href="http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf">http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf</a>

<sup>&</sup>lt;sup>17</sup> *Id*.

<sup>&</sup>lt;sup>18</sup> *Id*.

 $<sup>^{19}~</sup>Id$ 

Aside from newly emerging diseases, infection control programs are also faced with new strains of bacteria that are resistant to standard antibiotics.<sup>20</sup> According to the CDC,

[p]reventing the emergence and transmission of these pathogens requires a comprehensive approach that includes administrative involvement and measures (e.g., nurse staffing, communication systems, performance improvement processes to ensure adherence to recommended infection control measures), education and training of medical and other healthcare personnel, judicious antibiotic use, comprehensive surveillance for targeted MDROs [Multidrug-Resistant Organisms], application of infection control precautions during patient care, environmental measures (e.g., cleaning and disinfection of the patient care environment and equipment, dedicated single-patient-use of non-critical equipment), and decolonization therapy when appropriate.<sup>21</sup>

Hospitals understand that to protect patients, "they must take action to ensure that the risk of infection is minimized, and they are taking precautionary steps that range from the routine sterilization of instruments to the use of specialized ventilation systems to reduce the chance of the airborne spread of germs." These actions are taken to protect all patients as part of the health care services that the hospital provides. This Court need not take a liberal or expansive view of the MPLA to find that a hospital's infection control program falls within the MPLA. As these points make clear, "infection control is a highly technical and complex area of knowledge" as discussed in *Gahm*, supra, and is a crucial part of the health care that the patient receives while he or she is in the hospital. It is clearly and unequivocally an "act... performed or furnished, or which should have

<sup>&</sup>lt;sup>26</sup> See, AHA, Statement of the American Hospital Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigation Hearing. Public Reporting on "Hospital-Acquired Infections" Empowering Consumers, Saving Lives, March 29, 2006, available at <a href="http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf">http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf</a>.

<sup>&</sup>lt;sup>21</sup> See, CDC, Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007, available at, <a href="http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf">http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf</a>
<sup>22</sup> See, AHA, Statement of the American Hospital Association before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigation Hearing. Public Reporting on "Hospital-Acquired Infections" Empowering Consumers, Saving Lives, March 29, 2006, available at <a href="http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf">http://www.aha.org/aha/testimony/2006/060329-tes-aha-energycommerce.pdf</a>.

been performed or furnished, by any health care provider [which includes a health care facility] for, to or <u>on behalf of a patient</u> during the patient's medical care, treatment or confinement." W.Va. Code §55-7B-2(a)(Emphasis added).

D. <u>Amicus WVAJ's argument that hospital infection control is not health care if taken to its logical conclusion may leave hospitals with no insurance to cover claims of negligent infection control.</u>

WVAJ argues in its brief that infection control is akin to credentialing or building safety and corporate management. WVAJ asserts that general liability insurance will cover claims arising for any failures in a hospital's infection control activity. WVAJ amicus brief at 12. However, WVAJ is too quick with its rhetoric. Since the rise in mold, fungi and bacteria lawsuits, commercial general liability insurance have excluded claims related to fungi and bacteria. See Appendix, Exhibit C. In the attached "Fungi or Bacteria Exclusion," there is no insurance under the CGL policy for "contact with, exposure to, existence of, or presence of any "fungi" or bacteria on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury." Id. Exhibit C. If this Court adopts WVAJ's conclusion that infection control is not hospital health care, then medical liability carriers may seek to exclude hospital infection control claims from their policies, while CGL policies have already excluded claims related to the presence of bacteria. Such a perverse result is contrary to the public policy to protect the public served by health care providers, and to provide persons who suffer an injury with adequate and reasonable compensation by making available to hospitals, physicians and

other health care providers reasonably priced and extensive liability insurance. W.Va. Code  $\S$  55-7B-1.<sup>23</sup>

### **CONCLUSION**

Amici curiae, West Virginia Hospital Association and West Virginia State Medical Association, on behalf of their member hospitals, physicians, residents and medical students, urge this Court to affirm the order of the Circuit Court finding the MPLA applicable to the instant case, as a hospital's infection control activity is a health care service as defined by and bound by the requirements of the MPLA.

WEST VIRGINIA HOSPITAL ASSOCIATION AND WEST VIRGINIA STATE MEDICAL ASSOCIATION

By Counsel

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West Virginia Hospital Association West Virginia State Medical Association

WVAJ also attempts to argue that the malpractice crisis is solved; therefore, the MPLA need not be expanded beyond its terms. First, *Amici* argue that the issue on appeal does not require any expansion. The MPLA in its definition of health care includes any act rendered to or on behalf of a patient while that patient is confined within the hospital. *See infra*. Second, while these *Amici* are pleased that the WVAJ acknowledges that the tort reform is working, *Amici* wish to point out by analogy that much like a dam holds back water and makes life comfortable for all living below it, a serious breach in the dam destroys the good work of the dam.

# APPENDIX

### Westlaw.

Not Reported in F.Supp.2d Not Reported in F.Supp.2d, 2006 WL 473750 (N.D.W.Va.) (Cite as: Not Reported in F.Supp.2d)

Miller v. American Nat'l. Red Cross N.D.W.Va.,2006. Only the Westlaw citation is currently available. United States District Court,N.D. West Virginia.

James MILLER, Plaintiff, v.

THE AMERICAN NATIONAL RED CROSS, an organization chartered by Act of Congress and West Virginia University Hospitals, Inc., a West Virginia corporation, Defendants.

No. Civ.A. 1:05CV71.

Feb. 28, 2006.

Crystal Hawkins Castleberry, Stephen E. Hastings, Castleberry Law Offices, Morgantown, WV, for Plaintiff.

Mark A. Glover, Stephen B. Farmer, G. Kenneth Robertson, Farmer, Cline & Campbell, PLLC, Charleston, WV, Anne P. Davis, M. Sean Laane, Arnold & Porter, Washington, DC, Christine S. Vaglienti, WVU Hospitals, Inc., Morgantown, WV, for Defendants.

MEMORANDUM OPINION AND ORDER GRANTING WITHOUT PREJUDICE DEFENDANT WEST VIRGINIA UNIVERSITY HOSPITALS, INC.'S MOTION TO DISMISS

STAMP, J.

### I. Procedural History

\*1 On March 18, 2005, the plaintiff, James Miller ("Miller"), filed a complaint in the Circuit Court of Mongolia County, West Virginia alleging that the defendant, West Virginia University Hospitals, Inc. ("WVUH"), negligently provided blood tainted with malaria during a blood transfusion at Ruby Memorial Hospital in Morgantown, West Virginia. On April 19, 2005, WVUH removed the action to this Court pursuant to 28 U.S.C. § § 1441 and 1446.

On November 16, 2005, this Court held a status and scheduling conference. As agreed upon by the parties in the conference, this Court dismissed without prejudice WVUH's motion to dismiss that was filed in state court and entered a briefing schedule for WVUH to file a motion to dismiss if it deemed appropriate. WVUH filed a motion to dismiss, on

November 18, 2005, pursuant to Federal Rule of Civil Procedure 21(b)(6). The plaintiff responded and WVUH replied. WVUH's motion is fully briefed and ripe for review.

For the reasons state below, this Court finds that defendant WVUH's motion to dismiss should be granted without prejudice.

### II. Facts

WVUH is a health care facility pursuant to the laws of West Virginia engaged in the business of providing health care and medical services to the public. (Compl.¶ 3.)

On or about March 24, 2003, the plaintiff had a blood transfusion while undergoing a lung biopsy at WVUH. The blood used in the transfusion was collected, screened and/or provided to WVUH by The American National Red Cross ("Red Cross"). On or about January 22, 2004, the plaintiff was contacted by the Red Cross and informed, for the first time, that the blood he was given in his transfusion was tainted with malaria. The plaintiff argues that defendant WVUH breached its duty to properly collect, screen and/or prepare the blood provided to patients at Ruby Memorial Hospital. Plaintiff also argues that WVUH was negligent with respect to its policies and procedures utilized in order to ensure that the blood provided to the plaintiff during the blood transfusion was not tainted with malaria or other diseases or defects.

Plaintiff seeks compensatory damages, including damages for emotional and physical pain, humiliation, embarrassment, degradation, emotional distress, mental anguish, fear, shock, horror, annoyance, inconvenience and the loss of ability to enjoy life, punitive damages, with pre-judgment and post-judgment interest, and attorney's fees.

### III. Applicable Law

Defendant WVUH moves this Court to dismiss this case pursuant to Federal Rule of Civil Procedure 12(b)(6). In assessing a motion to dismiss for failure to state a claim under this Rule, a court must accept the factual allegations contained in the complaint as

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true. Advanced Health Care Servs., Inc. v. Radford Community Hosp., 910 F.2d 139, 143 (4th Cir.1990). Dismissal is appropriate pursuant to Rule 12(b)(6) only if "'it appears to be a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proven in support of its claim." 'Id. at 143-44 (quoting Johnson v. Mueller, 415 F.2d 354, 355 (4th Cir.1969)); see also Rogers v. Jefferson-Pilot Life Ins. Co., 883 F.2d 324, 325 (4th Cir.1989).

\*2 Stated another way, it has often been said that the purpose of a motion under Rule 12(b)(6) is to test the formal sufficiency of the statement of the claim for relief; it is not a procedure for resolving a contest about the facts or the merits of the case, 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1356, at 294 (2d ed.1990). The Rule 12(b)(6) motion also must be distinguished from a motion for summary judgment under Federal Rule of Civil Procedure 56, which goes to the merits of the claim and is designed to test whether there is a genuine issue of material fact. Id. § 1356, at 298. For purposes of the motion to dismiss, the complaint is construed in the light most favorable to the party making the claim and essentially the court's inquiry is directed to whether the allegations constitute a statement of a claim under Federal Rule of Civil Procedure 8(a). Id. § 1357, at 304, 310.

Finally, "[a] district court's dismissal under Rule 12(b)(6) is, of course, with prejudice unless it specifically orders dismissal without prejudice. That determination is within the district court's discretion." Carter v. Norfolk Community Hosp. Ass'n, 761 F.2d 970, 974 (4th Cir.1985).

### IV. Discussion

Defendant WVUH argues that this Court should dismiss the complaint because the plaintiff has stated a cause of action for medical professional liability but has failed to follow the requirements set forth in the West Virginia Medical Professional Liability Act, West Virginia Code § 55-7B-6 for bringing such a claim.

In response, the plaintiff argues that the allegations in his complaint do not fall within the scope of the West Virginia Medical Professional Liability Act, W. Va.Code § 55-7B-6, et seq.

In reply, defendant WVUH argues that the plaintiff was a patient at West Virginia University Hospitals, Inc. and received an allegedly tainted blood as part of a blood transfusion given to him, and thus, is covered under the West Virginia Medical Professional Liability Act.

### A. West Virginia Medical Professional Liability Act

According to the West Virginia Medical Professional Liability Act, West Virginia Code § 55-7b-2(d), et seq, medical professional liability is defined as "any liability for damages resulting from the death or injury of a person for any tort or breach of contract based on health care services rendered ... by a health care provider or health care facility to a patient."

### 1. Public Policy

In his complaint, plaintiff alleges the tort of negligence against WVUH for improper screening policies and handling of blood provided to the plaintiff while he undergoing a blood transfusion as a patient at WVUH. The plaintiff argues that his alleged injury is not a tort of negligence based on health care services rendered during a blood transfusion. Plaintiff asserts that he does not maintain that the blood transfusion was performed negligently.

This Court finds that the plaintiff is claiming that the collecting, screening and/or preparation of blood provided during the blood transfusion to the plaintiff was performed negligently. While the plaintiff is not arguing that the actual blood transfusion was negligently performed, he is arguing that the procedure for screening the blood that was provided as part of a health care service rendered to a patient was negligently screened, collected and/or prepared. Further, the plaintiff states that the defendant WVUH owes a duty not only to him but to "others similarly situated ..." (Pl.'s Resp. at 5.)

\*3 The public policy of the Medical Professional Liability Act states that, "as in every human endeavor the possibility of injury or death from negligent conduct commands that protection of the public served by health care providers be recognized as an important state interest." W. Va.Code § 55-7B-1. It is an important state interest to properly collect, screen and/or prepare blood that is used at a health care facility. Accordingly, plaintiff's complaint falls within the public policy interests of the West Virginia Professional Liability Act.

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### 2. Ordinary Negligence

Plaintiff argues that his claim is one of ordinary negligence because it regards the "duties of a hospital with respect to the handling of blood and blood related products." (Pl.'s Resp. at 4.) Plaintiff states that the court in Gray v. Mena, West Virginia Supreme Court of Appeals Opinion No. 32507 (2005), found that there are many causes of action that do not amount to medical malpractice, such as fraud, spoilation of evidence, negligent hiring, battery, larceny or libel. Further, plaintiff argues that this civil action is similar to the action in Doe v. American National Red Cross, 848 F.Supp. 1228 (1994),which related to the human immunodeficiency virus ("HIV") and the duties that the Red Cross and the hospital have in providing blood to patients.

On the other hand, defendant WVUH argues that Doe is not applicable because it applies to injuries that occurred before June 6, 1986. Plaintiff does note in his response that the analysis in Doe was related to the law prior to the enactment of the West Virginia Medical Professional Liability Act. Id. The plaintiff asserts that this does not affect its reasoning and the medical malpractice claim in this civil action should be treated the same as the claim in Doe. Defendant WVUH argues that the court in Doe acknowledged that the "clear and growing consensus of jurisdictions ... view the production and safeguarding of the nation's blood supply as a professional activity entitled to a professional standard of care." Doe. 848 F.Supp. at 1231. Accordingly, defendant WVUH argues that the hospital is required to provide a special standard of care, which has been codified in the West Virginia Medical Professional Liability Act. Thus, defendant WVUH asserts that the West Virginia Medical Professional Liability Act reflects the standard set forth in Doe. Id.

This Court finds that the plaintiff's analysis of *Doe* is not applicable to this civil action because: (1) the *Doe* case applies to injuries that occurred before June 6, 1986 and (2) since *Doe*, the legislature has enacted the West Virginia Medical Professional Liability Act, which clearly covers the plaintiff's claim in this civil action. *Id.* This Court also finds that this case is not a claim of ordinary negligence, such as fraud, spoilation of evidence, negligent hiring, battery, larceny or libel. *See Gray*, West Virginia Supreme Court of Appeals Opinion No. 32507.

\*4 Accordingly, plaintiff's complaint falls within the parameters of the Medical Professional Liability Act.

### B. Requirements for a Medical Professional Liability Action

Pursuant to West Virginia Code § 55-7B-6(a), a claimant must follow the prerequisites for filing an action against a health care provider. "At least thirty days prior to the filing of a medical professional liability action against a health care provider, the claimant shall serve ... a notice of claim on each health care provider the claimant will join in litigation." W. Va.Code § 55-7B-6(b). The notice shall include the theory or theories of liability, a list of all health care providers and facilities who will be receiving a claim and a screening certificate of merit executed by a qualified expert health care provider. Id. If the plaintiff believes that no screening certificate is necessary, then he or she must provide a statement setting forth the alleged legal theory that does not require supporting expert testimony. W. Va.Code § 55-7B-6(c).

In this civil action, the plaintiff has not followed the required procedures for filing an action against a health care provider under the Medical Professional Liability Act. The plaintiff has brought a claim alleging the tort of negligence but has not provided a screening certificate or, in lieu of the screening certificate, filed a statement regarding the reason why none is required. See W. Va.Code § 55-7B-6(b)(c). Thus, this case must be dismissed without prejudice and the plaintiff can bring his claim according to the above-stated requirements.

### V. Conclusion

For the reasons stated herein, the defendant West Virginia University Hospital, Inc.'s motion to dismiss plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) is hereby GRANTED WITHOUT PREJUDICE.

### IT IS SO ORDERED.

The Clerk is DIRECTED to transmit a copy of this memorandum opinion and order to counsel of record herein.

N.D.W.Va.,2006.
Miller v. American Nat'l. Red Cross
Not Reported in F.Supp.2d, 2006 WL 473750
(N.D.W.Va.)

Not Reported in F.Supp.2d Not Reported in F.Supp.2d, 2006 WL 473750 (N.D.W.Va.) (Cite as: Not Reported in F.Supp.2d)

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Gahm v. Thomas Jefferson University Hosp. E.D.Pa., 2000.

Only the Westlaw citation is currently available.
United States District Court, E.D. Pennsylvania.
Brian GAHM,

THOMAS JEFFERSON UNIVERSITY HOSPITAL, et al.

No. CIV. A. 94-2050.

February 29, 2000

### **MEMORANDUM**

LUDWIG.

\*1 Defendants Thomas Jefferson University Hospital, Sanford H. Davne, M.D. and Donald Myers, M.D. move for summary judgment. Fed.R.Civ.P. 56. FNI Jurisdiction is diversity. 28 U.S.C. § 1332.

FN1. "[S]ummary judgment should be granted if, after drawing all reasonable inferences from the underlying facts in the light most favorable to the non-moving party, the court concludes that there is no genuine issue of material fact to be resolved at trail and the moving party is entitled to judgment as a matter of law." Kornegay v. Cottingham, 120 F.3d 392, 395 (3d Cir.1997).

This is a medical malpractice case. On March 29, 1992, plaintiff Brain Gahm was involved in an automobile accident. On August 10, 1992, Gahm was seen by Dr. Davne, with complaints of numbness in his right leg and foot. The following day Gahm was admitted to Thomas Jefferson University Hospital for a CT Scan and Myelogram, which confirmed a herniated disc. On April 22, 1992, Doctors Davne and Myers performed elective fusion and implant surgery, using a so-called bone screw.

Soon after surgery, Gahm's temperature exceeded 102 degrees. He had an oral infection, chest wall blisters, an unhealed surgical wound and a hematoma with excessive drainage. Two months later, on June 16, 1992, he was discharged. His complaints are alleged to have persisted and to have resulted in residual physical impairment.

Plaintiff filed this action to recover for personal injuries attributable to the infection. According to the complaint, Doctors Myers and Davne implanted a defective medical screw in Gahm's spine. FN2 In addition, they, together with the hospital, failed to diagnose and properly treat a post-operative infection, allowing it to become chronic.

FN2. The issue of whether the screw was defective is moot, a class action settlement having been reached with the manufacturer, Acromed Corporation. See Pretrial Order 1117, Fanning v. AcroMed Corporation, MDL No. 1014, Civ. No. 97-381 (E.D.Pa. October 17, 1997).

Two counts remain-a negligence claim against the three defendants and a claim for informed consent against the two doctors. FN3

FN3. Upon motion, plaintiff's claim for intentional infliction of emotional distress was dismissed as uncontested. Order, August 26, 1999.

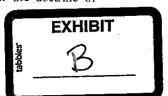
### I. Thomas Jefferson University Hospital

Plaintiff's infection is alleged to have been caused by the negligence of the hospital and its staff. FN4 Under applicable state law, FN5 professional negligence in the nature of medical malpractice consists of (1) a duty owed to plaintiff, (2) a breach of that duty by the physician, (3) a casual connection with plaintiff's harm, and (4) a direct link between the harm and plaintiff's damages. *Mitzelfelt v. Kamrin*, 526 Pa. 54, 62, 584 A.2d 888, 891 (1990).

FN4. Since the surgery was not performed by employees of the Thomas Jefferson University Hospital, plaintiff's claim against the hospital relates to the diagnosis and treatment of his infection.

FN5. It is undisputed that Pennsylvania law governs the substantive issues.

Hospitals may be held liable under the doctrine of



Page 2

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corporate negligence. See Thompson v. Nason Hosp., 527 Pa. 330, 591 A.2d 703 (1991). "This theory of liability creates a nondelegable duty which the hospital owes directly to a patient.... [and] an injured party does not have to rely on and establish the negligence of a third party." Id. at 339, 591 A.2d at 707. "The cause of action arises from the policies, actions or inaction of the institution itself, rather than the specific acts of individual hospital employees." Moser v. Heistand, 545 Pa. 554, 560, 681 A.2d 1322, 1326 (1996). The duty has been delineated into four categories:

- (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.
- \*2 Thompson, 527 Pa. at 339-340, 591 A.2d at 707 (citations omitted). "[P]laintiff is also required to present an expert witness who will testify, to a reasonable degree of medical certainty, that the acts of the physician deviated from good and acceptable medical standards, and that such deviation was the proximate cause of the harm suffered." See Mitzelfelt, 526 Pa. at 62, 584 A.2d at 892. The hospital must have "actual or constructive knowledge of the defect or procedures which created the harm." Thompson, 527 Pa. at 341, 591 A.2d at 708.

Plaintiff has presented expert reports from Doctors Holzman, Aragona, and McGuckin. Dr. Holzman notes that Meyers, "as well as [] others caring for Mr. Gahm," failed to consider the possibility of infection. Holzman Report at 7. The report of Dr. McGuckin states: "Gahm developed a hospital acquired infection at TJUH during his first admission on 4/22/92." McGuckin Report at 3. This evidence, plaintiff asserts, "necessarily implies a breach of the hospital's duty to use reasonable care in the maintenance of safe and adequate facilities and equipment as outlined in *Thompson*." Plaintiff's Response to Motion for Summary Judgment at 4.

Plaintiff's proffer as to the hospital is not sufficient to survive summary judgment. There is no basis for a finding that the hospital deviated from an appropriate standard of care. Dr. McGuckin is critical of the hospital for misclassifying the infection. However, she does not offer an opinion that the hospital was negligent or that the hospital's services, or lack of them, increased the chances of plaintiff's infection. See Mitzelfelt, 526 Pa. at 63-64, 584 A.2d at 892-93

citing Hamil v. Bashline, 481 Pa. 256, 269, 392 A.2d, 1280, 1286 (1978) (expert testimony required that defendant's action increased the risk of harm or injury).

This is a case in which expertise is essential. Expert medical testimony is necessary "when there is no common fund of knowledge from which laymen can reasonably draw the inference or conclusion of negligence." See Jones v. Harrisburg Polyclinic Hosp., 496 Pa. 465, 472, 437 A.2d 1134, 1138 (1981). It is not an obvious or commonplace set of circumstances in which the doctrine of res ipsa loquitur could allow the fact-finder to infer negligence and causation. See Jones, 496 Pa. at 471-475, 437 A.2d at 1137-39. Hospital infection control is a highly technical and complex area of knowledge. Accordingly, without an expert report stating that the hospital was negligent, the motion for summary judgment must be granted.

### II. Doctors Davne and Myers

Defendants Davne and Myers move for partial summary judgment on the counts of negligence and for summary judgment on the count of informed consent. FN6

FN6. Defendant Meyers filed his own motion and joined Dr. Davne's motion.

### A. Negligence

Davne and Myers move for summary judgment on the issue of negligence in the implantation of the bone screws-not on the issue of negligence related to diagnosing or controlling the infection. Since plaintiff does not attempt to support the claim that bone screw implantation was negligently performed, summary judgment will be granted as to that issue.

#### B. Informed Consent

\*3 Lack of informed consent requires "expert information as to the nature of the harm which may result and the probability of its occurrence." Jozsa v. Hottenstein, 364 Pa.Super. 469, 473, 528 A.2d 606, 607-608 (1987). "Once expert medical testimony establishes that there was a risk of any nature to the patient that he or she was not informed of, and after surgery the patient suffers from that undisclosed risk,

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it is for the jury to decide whether the omission was material to an informed consent." *Id.* at 474, 528 A.2d at 608. In addition, expert testimony is required to "establish[] the causative element." *Maliszewski v. Rendon,* 374 Pa. Super. 109, 115, 542 A.2d 170, 173 (1988).

Plaintiff contends that his consent was not informed because he was not advised of: (1) the investigative nature of the surgery, (2) the stock options the doctors owned with the bone screw manufacturer, (3) the risk of an "investigational" device being implanted in his spine, and (4) the experimental aspects of the procedure of which he was a part. See Plaintiff's Responses to Doctors' Motion for Summary Judgment. These assertions generally arise from the use of non-FDA approved bone screws during surgery. However, on October 17, 1997, a class-wide settlement between the Plaintiffs' Legal Committee and AcroMed Corporation received court approval. See Pretrial Order 1117. The settlement included those claims-

based in whole or part on products liability theories, including claims based upon the regulatory status of the device .... claims for failure to warn of the regulatory status of the device .... includ[ing] informed consent claims based on failure to disclose regulatory status.

Joint Statement of the Factual and Procedural History and Status of Remaining Claims at 3, March 26, 1999. As a result, the only ground left for lack of informed consent is the doctors' alleged failure to apprise plaintiff of the increased likelihood of infection.

While it is unclear what plaintiff was told or was made aware of prior to consenting to surgery, FN7 plaintiff has not produced expert opinion on either the nature of the risk of infection or the probability of its occurrence. The sole expert submission that arguably concerns these points is Dr. Holzman's statement that "the risk of infection during the spinal surgery of April, 1992 was increased by the prior use of corticosteroids." Holzman Report at 6. His report does not adequately consider or discuss the risk of infection or its probability. Moreover, it leaves unanswered whether the use of corticosteroids was the cause, or contributed to the cause, of the infection or the extent to which it purportedly increased the risk. Plaintiff having the burden of proof at trial has not come forward with sufficient probative evidence to constitute a genuine issue of material fact on informed consent.

FN7. No evidence has been presented as to whether plaintiff did or did not sign a surgery consent form. At his deposition, plaintiff conceded he was aware of the risk of surgical infection; however, he further stated he was "led to believe that it was a very low percentage." Deposition of Brian R. Gahm at 182, October 6, 1995.

#### ORDER

AND NOW, this 29th day of February, the following is ordered:

\*4 1. Defendant Thomas Jefferson University Hospital's motion for summary judgment is granted; 2. The motions of Sanford H. Davne, M.D. and Donald Myers, M.D. for partial summary judgment are granted.

E.D.Pa.,2000. Gahm v. Thomas Jefferson University Hosp. Not Reported in F.Supp.2d, 2000 WL 233247 (E.D.Pa.)

END OF DOCUMENT

### THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

### **FUNGI OR BACTERIA EXCLUSION**

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

A. The following exclusion is added to Paragraph 2... Exclusions of Section I - Coverage A - Bodily injury And Property Damage:

#### 2. Exclusions

This insurance does not apply to:

### Fungi or Bacteria

- a. "Bodily injury" or "property damage" which would not have occurred, in whole or in part, but for the actual, alleged or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of, any "fungi" or bacteria on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury or damage.
- b. Any loss, cost or expenses arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to, or assessing the effects of, "fungi" or bacteria, by any insured or by any other person or entity.

This exclusion does not apply to any "fundi" or bacteria that are, are on, or are contained in, a good or product intended for consumption.

B. The following exclusion is added to Paragraph 2., Exclusions of Section I - Coverage B - Personal And Advertising Injury Liability:

### 2. Exclusions

This insurance does not apply to:

### Fungi or Bacteria

- a. "Personal injury" or "advertising injury" which would not have taken place, in whole or in part, but for the actual, alleged or threatened inhalation of, ingestion of, contact with, exposure to, existence of, or presence of any "fungi" or bacteria on or within a building or structure, including its contents, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such injury.
- b. Any loss, cost or expenses arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to, or assessing the effects of, "fungi" or bacteria, by any insured or by any other person or entity.
- C. The following definition is added to the Definitions Section:

"Fungi" means any type or form of fungus, including mold or mildew and any mycotoxins, spores, scents or byproducts produced or released by fungl.

### **CERTIFICATE OF SERVICE**

This is to herby certify that on this 27<sup>th</sup> day of July, 2007, the undersigned have served a true and exact copy of the forgoing "AMICI BRIEF IN SUPPORT OF BRIEF OF APPELLEE, WEST VIRGINIA UNIVERSITY HOSPITALS, INC." via United States Mail, postage properly paid, upon the following:

Christine S. Vaglienti Associate Litigation Counsel WEST VIRGINIA UNIVERSITY HOSPITALS, INC. P.O. Box 8128 Morgantown, WV 26506-8128 Counsel for Appellee	Rita Massie Biser KAY CASTO & CHANEY, PLLC P.O. Box 2031 Charleston, WV 25327 Counsel for Appellee
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